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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,635	01/10/2002	Kevin M. Moore	1533.0980002	6960
26111	7590	02/26/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005				NAFF, DAVID M
ART UNIT		PAPER NUMBER		
		1651		

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.A.M.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/041,635	MOORE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 November 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 32 and 36-45 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 32 and 36-45 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

***Response to Amendment***

The amendment of 11/24/03 amended claim 32 and canceled claims 33-35.

Claims examined on the merits are 32 and 36-45, which are all 5 claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 103***

Claims 32 and 36-45 are rejected under 35 U.S.C. 103(a) as being 10 unpatentable over Dumpermann et al (5,852,211) in view of Bott et al (0 174 624).

The claims are drawn to recovery of an organic acid ester from a fermentation broth by drying the broth without prior removal of insolubles to produce a dried product, adding the dried product to a 15 lower alcohol in the presence of an acid to obtain free organic acid, esterifying the free organic acid to the corresponding ester, and removing insolubles to obtain an organic acid ester. The organic acid can be 2-keto-L-gulonic acid and the acid present when the dry product is added to the lower alcohol can be sulphuric acid.

20 Dumpermann et al disclose a process for obtaining 2-keto-L-gulonic acid (KGA) from a fermentation solution containing the sodium salt of 2-keto-L-gulonic acid (NaKGA) that results from neutralization. The process involves crystallizing the sodium salt (NaKGA) and separating the resulting crystals from the fermentation 25 solution, suspending the NaKGA crystals in a lower alcohol acidified

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to a pH of about 1.5 to about 3.5 with an acid such as sulphuric acid where the acid is converted to an insoluble sodium salt and the NaKGA is converted to free KGA, and removing the insoluble sodium salt of the acid to obtain an alcoholic solution of the KGA. Afterwards, the  
5 free KGA may be esterified by alcohol of the alcoholic solution in the presence of a catalytic amount of acid to obtain an alkyl ester of the KGA. For example, see col 4, lines 10-33, and Examples 1-3.

Bott et al disclose producing alkyl lactate esters by filtering a crude fermentation mixture containing calcium lactate, spray drying  
10 the resulting filtrate to obtain solid calcium lactate, reacting the solid calcium lactate with an alcohol in the presence of an acid that forms a water-soluble calcium salt and isolating the lactic acid ester formed.

It would have been obvious to omit crystallizing NaKGA in the  
15 process of Dumpelmann et al and instead dry the fermentation broth and react the dried broth with the lower alcohol in the presence of acid as suggested by Bott et al using steps of drying a fermentation solution without crystallizing in the production of a lactic acid ester from a fermentation mixture containing a calcium salt of the  
20 lactic acid. Drying without crystallizing would have been expected to simplify the process of Dumpelmann et al, and such simplification would have been motivation to use drying in place of crystallizing and separating the crystals. While Bott et al filter the fermentation broth, it would have been obvious to omit filtering to further  
25 simplify. There is seen nothing to lead one to believe that the

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reacting of NaKGA as disclosed by Bott et al cannot occur in an unfiltered fermentation broth. Furthermore, the fermentation broth dried in claim 32 without prior removal of insolubles can be a fermentation broth from which cells have been removed by filtration 5 prior to drying in step (a). Claim 32 does not specify how the fermentation broth required in the claim preamble is prepared.

In Dumpelmann et al, free KGA can be converted to an ester, and to form the ester followed by removing insolubles would have merely depended on individual preference for the ester instead of free KGA. 10 The conditions of dependent claims would have been matters of obvious choice in view of the disclosures of the references.

***Response to Arguments***

Applicant's arguments filed 11/24/03 have been fully considered but they are not persuasive.

15 In a 37 C.F.R. 1.132 Declaration of Kevin M. Moore and remarks in the amendment, it is urged that Bott et al must remove biomass since the process of Bott et al would not work in the presence of biomass. It is further pointed out that Dumpelmann et al et al crystallize gulonate from a fermentation solution and does not suggest drying of a 20 fermentation broth without removing biomass.

This argument is unpersuasive since the present claims do not exclude preparing the broth required in the preamble of claim 32 by a process including removing cells (biomass) such as by filtration. The claim does not set forth how the initial fermentation broth that is 25 dried is prepared. In example 1 in the specification, the broth is

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prepared as described in U.S. Patent 5,834,231. This patent describes preparing the broth by a process that includes a step of centrifugation or filtration to remove cells (col 7, lines 1-5). This disclosure indicates that the broth dried in example 1 is a broth from which cells have been removed. If the broth of the claims that is dried is intended to contain all cells used in fermentation without any separation of cells and other insolubles, the claims should require before step (a) a step of fermenting with cells to obtain a broth containing insolubles including all cells used in fermenting, and then require drying the broth without removing any of the insolubles in the broth after fermenting. Even claim 32 requires not removing any cells prior to drying, the patent ('231) discloses (col 6, lines 59-62) that 2-KGL accumulates in the cells. It would have been obvious to not remove cells prior to drying to obtain the 2-KGL in the cells.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

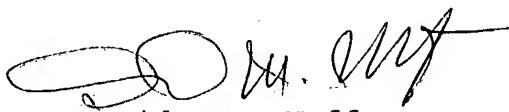
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff 5 whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this 10 application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for 15 unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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David M. Naff  
Primary Examiner  
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